replaced by new Claims 31-52. The new claims are believed to more clearly define applicants' invention and clarify language and distinctions with respect to the art.

It is noted that all but three of the claims submitted in the parent application stand rejected under 35 U.S.C. §103 as being unpatentable over several Politano and Politano et al publications in view of Ersek, et al. all previously cited in that application, Ersek et al. having not been previously applied. It is the Examiner's position that a process for treating urinary or gastric disorders is generally disclosed by Politano and that Ersek et al. recognize the problems with migration of injected material and studied the effects of texturized particles for augmenting soft tissue in which tissue growth about the particles increased particle retention in the area of augmentation. Therefore, it follows that it would have been obvious to use texturized particles in the treatment of urinary incontinence.

Applicants do not believe that this is the case. Applicants were careful to point out in their earlier response (paper no. 7) that the success obtained by the injection of polytetrafluoroethylene (PTFE) micro particulate matter with respect to long term alleviation of urinary incontinence, and other chronic disorders, has been far from uniform. Much subsequent documented experience indicates the existence of serious drawbacks with respect to particulate migrations and subsequent granulomatous reactions as reported by Malizia, Jr. et al cited in applicants'

previous amendment. It is believed that there is, in fact, a high degree of unpredictability with regard to any such micro particulate injection treatments.

While the Ersek et al reference reports successful augmentation of soft tissue of the face and extremities using an injectable composition including textured micro implants, it clearly does not deal with the long-term augmentations of tissues related to correcting urological and gastric disorders such as incontinence or reflux. Applicants submit that, in view of the limited success of Politano with respect to the injection of particulate matter at all, the recognition by Ersek et al. that textured micro implants may be used to augment a certain class of soft tissues, in a manner which precludes migration of the particles, does not make it obvious that the textured micro implants would be successful in the treatment of the afore-mentioned urological and gastric disorders.

Applicants believe that the obviousness suggested with respect to the present invention is a retrospective conclusion rather than a reason based on the teachings in the art. It is believed that only through hindsight and given the teachings of the present specification that the suggested combination could be seen as obvious.

With respect to the three claims directed toward the use of polyvinylpyrrolidone (PVP) as an injection vehicle, now Claims 37, 47 and 51, and it is believed that these claims are clearly

patentable and not rendered obvious by the above combination or by that combination further in view of the newly-applied Henderson et al reference in U.S. Patent 4,828,827. That reference discloses an aqueous gel of cross-linked PVP used to augment soft tissue in mammals. It is clear that the PVP of the present invention is meant to be a vehicle only and not to participate in the long-term tissue augmentation. How the cross-linked PVP tissue augmentation material of Henderson et al. would, in that hydrogel state, function in replacing the glycerine and polysorbate found in the Politano et al. composition, it is submitted, cannot be predicted with any reasonable certainty. In any event, clearly no reason would be derived from a careful reading of the Politano references which would lead one to replace the glycerine and polysorbate combination with PVP. This is true after studying all of the references including Henderson et al inasmuch as lubricity and biocompatibility are clearly not problems with respect to the glycerine and polysorbate materials of Politano. There is no reason one would be led to make the suggested combination or substitution based on the references, therefore, it is believed no prima facia case of obvious can be maintained.

Applicants believe that present amendments have clarified distinctions between their claimed invention and the prior art and that their particular process or method including the particular composition injected, represents a definitive step forward over prior methods of treating the chronic problems involved. The

success of this approach is believed to be something that could not accurately be predicted based on the cited teachings and presents significant steps forward. It is believed that the present claims distinguish and reconsideration and early allowance of them is requested.

Respectfully submitted,

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